DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration Rockville MD 20857

MAY -4 2000 5887 '00 MAY -9 P1:46

The Honorable Mark E. Souder House of Representatives Washington, D.C. 20515-1404

Dear Mr. Souder:

Thank you for your interest in the Food and Drug Administration's (FDA or the Agency) regulatory proposal for safe handling labeling for eggs. You suggest that FDA's proposed safe handling labeling " . . . uses language that would alarm consumers without educating them . . . " You further suggest that the situation has changed substantially since FDA published the labeling proposal, in that the Egg Safety Action Plan had not been formulated. Furthermore, the Agency has an opportunity to examine a number of alternatives, including that proposed by the United Egg Producers in comments last year.

FDA plans to publish the labeling and refrigeration rules later The proposed safe handling statement is not intended to discourage consumers from buying eggs. The purpose of the proposed safe handling statement for eggs is to give consumers ways to reduce their risk, without having to avoid the product. We tentatively concluded that to adequately inform consumers of ways to reduce their risk, there was a need to include information on why there was a risk associated with consumption of raw or improperly cooked eggs. We received several comments on the proposed safe handling statement that are similar to yours and intend to address these comments when we take final action in this rulemaking.

We consider all of the issues and concerns mentioned in your letter as important. The Egg Safety Action Plan implementation will consider these matters as we develop our proposed regulations for on-farm and final regulations for retail national standards for shell egg producers. Likewise, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) is crafting companion national standard covering packers/processors. The proposed rules will be subject to public review and comment and are expected to be published in the fall. Public meetings

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were held on March 30 in Ohio and April 6 in California to discuss what might be included in proposed standards.

The information obtained at the public meetings and during the comment period following the meetings will be carefully considered as the proposed regulations are crafted. The meetings have assisted FDA and FSIS in obtaining information on what technology and procedures are available and practical for reducing or eliminating the risk of Salmonnella Enteritidis (SE) in eggs. Likewise, we appreciate your participation in this process.

Currently we are reviewing the comments we have received on the proposed labeling and refrigeration rules. Your comments will be considered along with all other comments received in response to the proposed rules in developing practical and effective public health measures to reduce illnesses associated with shell eggs. As noted above, FDA plans to publish final rules on labeling and refrigeration later this year.

We appreciate your concerns and look forward to working with industry, States, consumers, and our Federal counterparts in developing nationwide consistent standards to reduce SE illnesses associated with eggs.

Thanks again for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier Associate Commissioner

for Legislation

cc: Dockets Management Branch

MARK E. SOUDER

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Washington, DC 20515

March 22, 2000

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Honorable Jane E. Henney, Commissioner Food and Drug Administration Parklawn Building 5600 Fishers Lane Rockville, Maryland 20857

Dear Commissioner Henney:

Last July, the Food and Drug Administration proposed a warning label for eggs. Egg producers, while supporting the concept of safe handling labels, expressed strong opposition to the FDA's proposal, which the *Los Angeles Times* of January 5, 2000, described as "a tobaccostyle label."

It is easy to see both why the *Times* used this description and why egg producers were united in their opposition. The label uses language that would alarm consumers without educating them, as demonstrated by consumer polling conducted by the American Egg Board. These surveys found that consumers retained the message that eggs can be dangerous, but did not generally recall messages about proper handling techniques. Surely that is not the effect FDA would want.

Since the label was proposed the Administration has published an Egg Safety Action Plan. This plan calls for several comprehensive steps to mandate quality assurance programs, Salmonella testing and other on-farm actions.

There is room for debate about several aspects of the Administration's action plan, and producers have objected to certain features of the proposal. It is not my purpose in this letter, however, to address the merits of the plan. Instead, I simply want to suggest to you that the situation has changed substantially since the FDA proposed the warning label last year. When your agency issued its proposal the Egg Safety Action Plan had not been formulated.

In the context of the more comprehensive approach envisioned in the action plan, it is perhaps timely for the FDA to re-evaluate its earlier proposed warning label. Warnings that your agency might have found justified last summer may now be unnecessary or inappropriate even under the terms of your analysis. You have an opportunity to give further thought to the most effective safe handling label, as well as to examine a number of alternatives, including that proposed by the United Egg Producers in comments filed last year.

I will appreciate your personal attention to this matter. Food safety is a critically important subject of public policy, and I believe egg producers are as committed to ensuring a

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safe product as you and I. In the case of labels, our aim should be to encourage appropriate consumer behavior, not discourage people from buying eggs.

I look forward to a response at your earliest convenience.

Sincerely,

Mark Souder

Member of Congress

Mark Souder